

**BARCLAY DAMON** LLP

**Douglas J. Nash**  
*Partner*

September 2, 2015

**VIA CM/ECF**

Hon. David E. Peebles  
United States Magistrate Judge  
Federal Building and U.S. Courthouse  
100 South Clinton Street  
Post Office Box 7345  
Syracuse, New York 13261-7367

Re: Welch Allyn, Inc. v. OBP Corporation and OBP Medical Inc.  
Civil Action No. 5:14-cv-1122-TJM-DEP

Dear Judge Peebles:

Pursuant to the Text Minute Entry dated August 19, 2015, we write on behalf of the plaintiff, Welch Allyn, Inc. (“Welch Allyn”) to provide supplemental briefing regarding the arguments concerning prosecution history raised by defendants OBP Corporation and OBP Medical Inc. (collectively, “OBP”) for the first time during the *Markman* hearing held on August 19, 2015.

Claim 9 in the ‘175 Patent requires that the claimed speculum include “a lever portion extending from a proximal end of said upper blade and defining an opening” and “in which said [portable] illumination assembly is accessed for at least one of energization of said at least one LED and removal through said opening.” The claim requires that the speculum has to be configured so that the portable illumination assembly can be accessed and/or is accessible for energization and/or removal through the opening defined by the lever portion of the upper blade. Thus, infringement of Claim 9 occurs when a speculum is made, used, sold or imported that includes a portable illumination assembly that is accessible for energization and/or removal through the defined opening.

At the *Markman* hearing, and as shown below, OBP cited to an amendment made to Claim 9 during the prosecution of the patent and argued for the first time that as a result of “wording that Welch Allyn disclaimed by amendment during prosecution[,]” the phrase “‘is accessed’ . . . requires someone to perform the action” and is therefore invalid under *IPXL Holdings, LLC v. Amazon.com, Inc.*, 430 F.3d 1377 (Fed. Cir. 2005).

Hon. David E. Peebles  
 September 2, 2015  
 Page 2

92

Prosecution  
History  
Disclaimer

“is accessible”  
deleted and  
replaced with “is  
accessed”

11. (Currently Amended) A vaginal speculum apparatus, said apparatus comprising:

a portable illumination assembly comprising a portable power source ~~[[and]]~~, at least one LED, and a mechanism for energizing said at least one LED are retained within a common housing; and

a vaginal speculum having an upper blade ~~[[and]]~~ a lower blade, ~~each of said upper and lower blades having a distal end and an opposing proximal end~~, and a mechanism disposed at a proximal end of said ~~upper and lower blades~~ speculum for permitting relative movement between said upper blade and said lower blade to enable dilation of a patient, said movement mechanism including a lever portion extending from a proximal end of said upper blade and defining an opening, said portable illumination assembly being entirely contained within attached to the proximal end of one of said upper blade and said lower blade and releasably attached thereto and in which such that said illumination assembly is accessed for at least one of energization of said at least one LED and removal accessible through [[a]] said opening viewing aperture defined in the proximal end of said upper blade

Dkt, 39-6, p. 64, Amendment to pending claim 11 (patent claim 9)

(See OBP’s *Markman* Presentation, Slide 92 (citing to Dkt. 39-6, the Supplemental Response/Preliminary Amendment to RCE, dated Dec. 18, 2012 (“Response”).)

Despite having been the one to raise this issue, when pressed by the Court at the *Markman* hearing to explain why this amendment was made or to put the amendment into its proper context, OBP had no answer:

THE COURT: What do you understand the Patent and Trademark Office’s issue was in citing the two patents that caused Welch Allyn to move away from “is accessible” to “is accessed”?

MR. JENSEN: **We can’t precisely determine that** because a lot of this was based on the telephone interview and the notes of that telephone interview were not clear as to what the examiner’s objections were. One of those two patents did describe an opening like this that was similar at the back of the device, **so I don’t know**. But I do know that in response to that rejection on an obviousness ground and in response to the telephone interview with the examiner, that Welch Allyn very specifically went back, removed the phraseology “is accessible” and

Hon. David E. Peebles  
 September 2, 2015  
 Page 3

substituted the words “is accessed” and then claimed that that language, those amendments cured the problem and overcame the prior art references that were being cited against it.

(Transcript of *Markman* Proceeding, Aug. 19, 2015, pp. 103-04 (emphasis added).)<sup>1</sup>

OBP’s clear, and frankly misleading, implication was that the reason the claim was amended was to distinguish the invention from the prior art by requiring that a user actually access the portably illumination assembly. That is demonstrably false, and it appears that OBP used a surprise attack at the *Markman* hearing in the hope that Welch Allyn would not be able to effectively respond and point out that the very same prosecution history relied on by OBP, when not excerpted out of context on a PowerPoint slide, directly contradicts OBP’s position with respect to Claim 9.

As an initial matter, for prosecution history disclaimer to apply, as acknowledged by OBP, the patentee’s actions “surrender[ing] claim scope during the course of prosecution . . . must be clear and unmistakable.” (See OBP’s *Markman* Presentation, Slides 89-90 (quoting *Heuft Systemtechnik GmbH v. Indus. Dynamics Co.*, 282 Fed. Appx. 836, 839 (Fed. Cir. 2008).) *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003) (“for prosecution disclaimer to attach, our precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable”); *Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 493 F.3d 1358, 1365 (Fed. Cir. 2007) (alleged prosecution disclaimer did not “constitute a sufficiently clear and deliberate statement to meet the high standard for finding a disclaimer of claim scope”). In this case, there is nothing to suggest a “**clear and unmistakable**” disavowal of a speculum with a portable illumination assembly that **can be accessed and/or is accessible** for energization and/or removal through the opening defined by the lever portion of the upper blade in favor of a speculum where the portable illumination assembly must actually be accessed through the opening by some unclaimed user. Instead, as Welch Allyn explained at the hearing, the claim was amended to make clear that, unlike in the prior art of record, the portable illumination assembly can be accessed through the opening. The amendment had nothing to do with requiring a user to actually access the portable illumination assembly.

Specifically, the Response explained that:

**“Regarding claim 11 [Patent Claim 9], this claim has now been amended to specify the portable illumination assembly is accessible through an opening defined at the proximal end of the upper and lower blade . . . . In the present embodiment, and as clearly shown in Figs. 35-37 and paragraphs [00139] – [0142], when attached to one of the upper and lower blades, the portable illumination assembly is entirely contained within the proximal end of one of the upper and lower blades and releasably attached thereto such that the illumination**

---

<sup>1</sup> Attached as Exhibit A is an excerpt of the transcript from the *Markman* hearing.

Hon. David E. Peebles

September 2, 2015

Page 4

assembly **is accessed** for at least one of energization of the at least one LED and removal through the opening. Therefore, no new matter has been added.

As previously discussed, Moore describes an adaptive light carrier element that permits a diagnostic instrument handle to be used in conjunction with a vaginal speculum. The adaptive element, which retains a plurality of optical fibers, is inserted into a receiving cavity in the handle portion of the speculum and the light source separately contained in the instrument handle. **Claim 11 [Patent Claim 9], as amended, clearly requires that the portable illumination assembly comprising a portable power supply and at least one LED retained within a common housing be accessible through the opening defined in the proximal end of the speculum and more specifically, the upper and lower blades.** The speculum of Moore includes a similar opening, but clearly the illumination assembly cannot possibly be accessed through the defined opening, see Fig. 9 of Moore, whether for energization or removal.

The supplemental teachings of Wawro fail to include or even suggest the above-noted missing features. Even if one were to arguably interpret the LED and battery of this secondary reference provide an illumination assembly per se', [sic] accessing either would require removing the above components through the handle. **Access via an opening defined in the proximal end of the Moore speculum would be impossible. Therefore and because this recited feature is entirely missing from the cited prior art, amended claim 11 [ Patent Claim 9] is patentably distinct . . . .**

(Response, Dkt. 39-6, pp. 71-72 (emphasis added).)

Thus, the basis for the amendment was that, in contrast to the illumination assembly in the prior art Moore speculum, which is **impossible** to access via an opening defined in the proximal end, the portable illumination assembly in Claim 9 **is capable of being accessed** through an opening at the proximal end. That is, not only does the Response make clear that the reason for the amendment was to distinguish prior art in which the portable illumination assembly could **not** be accessed through the opening, but more importantly it explains the amendment itself **using the same language Welch Allyn has used in its proposed construction.** Indeed, the Response makes clear that the amendment was made to clarify that "the portable illumination assembly **is accessible** through [the] opening" and that the claim, as amended, require that "the portable illumination assembly . . . **be accessible** through the opening . . . ." That is essentially Welch Allyn's proposed construction, and it directly contradicts OBP's interpretation of Claim 9. It is concerning that OBP did not mention any of these facts, especially where the issue was being raised by OBP for the first time at the hearing and where the Court asked OBP to explain the reason for the amendment.

Hon. David E. Peebles

September 2, 2015

Page 5

In any event, Welch Allyn's proposed construction, which properly uses functional language to describe a structure (*i.e.*, the opening defined by a lever portion and proximal end of the upper blade) that is configured to be capable of performing the identified functions (*i.e.*, allowing access to the portable illumination assembly for energization and/or removal) is fully supported by the prosecution history and should be adopted, while OBP's arguments concerning prosecution disclaimer and indefiniteness should be rejected. *See Papst Licensing GmbH & Co. KG v. Fujifilm Corp.*, 778 F.3d 1255, 1261 (Fed. Cir. 2015) (reversing and holding that the prosecution history "informs the determination of claim meaning"); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) ("the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention"); *Creative Integrated Sys. v. Nintendo of Am., Inc.*, 526 Fed. Appx. 927, 934 (Fed. Cir. 2013) (vacating judgment of non-infringement; reliance on isolated statement in prosecution history to support a contrary construction was in error where there was no "clear and unambiguous disavowal . . . especially given the presence in this office action of numerous amendments and explanations . . . not similarly limited in scope").

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Douglas J. Nash", with a long horizontal flourish extending to the right.

Douglas J. Nash

cc: Counsel of Record (via CM/ECF)